IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF MISSISSIPPI
SOUTHERN DIVISION

CAROLYN MONTIFORTE	**PLAINTIFF**
v.	**CIVIL ACTION NO. 1:07cv967 LG-JMR**
PFIZER, INC., G.D. SEARLE, LLC, PHARMACIA CORPORATION MONSANTO COMPANY, LANCE ST. AMANT, RITA NOWELL, CHRISTINE RANSOM, MICKEY RUMSEY, and fictitious Defendants A, B, C and D.	**Pending Transfer to MDL-1699 (In re Bextra and Celebrex Marketing, Sales Practices and Products Liability Litigation)**
	DEFENDANTS

DEFENDANTS' ANSWER AND DEFENSES TO PLAINTIFF'S COMPLAINT

NOW COME Defendants Pfizer Inc. (improperly captioned in Plaintiff's Complaint as "Pfizer, Inc.") ("Pfizer"), Pharmacia Corporation (f/k/a Monsanto Company[1]) ("Pharmacia"), G.D. Searle LLC (improperly captioned in Plaintiff's Complaint as "G.D. Searle, LLC." ("Searle"), Rita Nowell, and Mickey Rumsey, and file this Answer to Plaintiff's Complaint ("Complaint"), and would respectfully show the Court as follows:

I.
PRELIMINARY STATEMENT

The Complaint does not state in sufficient detail when Plaintiff was prescribed or used Bextra® (valdecoxib) ("Bextra®"). Accordingly, this Answer can only be drafted generally.

[1] Plaintiff's Complaint names "Monsanto Company" as a Defendant. Defendants state that in 1933, an entity known as Monsanto Company ("1933 Monsanto") was incorporated under the laws of Delaware. On March 31, 2000, 1933 Monsanto changed its name to Pharmacia Corporation. On February 9, 2000, a separate company, Monsanto Ag Company, was incorporated under the laws of Delaware. On March 31, 2000, Monsanto Ag Company changed its name to Monsanto Company ("2000 Monsanto"). The 2000 Monsanto is engaged in the agricultural business and does not and has not ever designed, produced, manufactured, sold, resold, or distributed Bextra®. Given that Plaintiff alleges in her Complaint that Monsanto Company was involved in distributing Bextra®, *see* PLAINTIFF'S COMPLAINT at ¶ 7, Defendants assume Plaintiff means to refer to 1933 Monsanto. As a result, Pharmacia will respond to the allegations directed at Monsanto Company.

Defendants may seek leave to amend this Answer when discovery reveals the specific time periods in which Plaintiff was prescribed and used Bextra®.

II.

ORIGINAL ANSWER

1. Defendants state that this paragraph of the Complaint contains legal contentions to which no response is required. To the extent that a response is deemed required, Defendants admit that Plaintiff brought this civil action seeking monetary damages, but deny that Plaintiff is entitled to any relief or damages. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Bextra® and, therefore, deny the same. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

2. Defendants admit that Plaintiff claims to be a resident of the State of Mississippi. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding Plaintiff's age, and, therefore, deny the same.

3. Defendants admit that Plaintiff claims to be a resident of the State of Mississippi. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding Plaintiff's age, and, therefore, deny the same. Defendants deny that Bextra® caused Plaintiff injury or damage and deny the remaining allegations in this paragraph of the Complaint.

4. Defendants admit that Pfizer is a Delaware corporation and that Pfizer is registered to do business in Illinois. Defendants admit that Pfizer may be served through its registered agent. Defendants admit that, during certain periods of time, Pfizer marketed and co-promoted Bextra® in the United States to be prescribed by healthcare providers who are by law authorized to

prescribe drugs in accordance with their approval by the FDA. Defendants deny the remaining allegations in this paragraph of the Complaint.

5. Defendants admit that Searle is a Delaware limited liability company with its principal place of business in Illinois. Defendants admit that Pharmacia acquired Searle in 2000 and that, as the result of a merger in April 2003, Searle and Pharmacia became subsidiaries of Pfizer. Defendants admit that Searle may be served through its registered agent. Defendants admit that, during certain periods of time, Bextra® was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and distributed Bextra® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants deny the remaining allegations in this paragraph of the Complaint.

6. Defendants admit that Pharmacia is a Delaware corporation with its principal place of business in New Jersey and that Pharmacia is registered to do business in the State of Mississippi. Defendants admit that Pharmacia may be served through its registered agent. Defendants deny the remaining allegations in this paragraph of the Complaint.

7. Defendants admit that in 1933 an entity known as Monsanto Company ("1933 Monsanto") was incorporated under the laws of Delaware. On March 31, 2000, a subsidiary of 1933 Monsanto merged with Pharmacia & Upjohn, Inc, and 1933 Monsanto changed its name to Pharmacia Corporation. On February 9, 2000, a separate company, Monsanto Ag Company, was incorporated under the laws of Delaware. On March 31, 2000, Monsanto Ag Company changed its name to Monsanto Company ("2000 Monsanto"). The 2000 Monsanto is engaged in the agricultural business and does not and has not ever manufactured, marketed, sold, or distributed Bextra®. The 2000 Monsanto is not and has never been the parent of either Searle or Pharmacia. As the 2000 Monsanto does not and has not ever manufactured, marketed, sold, or distributed Bextra®, Defendants therefore state that the 2000 Monsanto is not a proper party in this matter. Defendants deny the remaining allegations in this paragraph of the Complaint. Defendants state that the response to this paragraph of the Complaint regarding Monsanto is incorporated by

reference into Defendants' responses to each and every paragraph of the Complaint referring to Monsanto and/or Defendants.

8. Defendants state that the allegations in this paragraph of the Complaint regarding Lance St. Amant are not directed toward Defendants and, therefore, no response is required.

9. Defendants state that this paragraph of the Complaint contains legal contentions to which no response is required. To the extent that a response is deemed required, Defendants admit that Rita Nowell was employed by Pfizer as a pharmaceutical sales representative and, at times, called on certain healthcare providers regarding Pfizer's products. Defendants admit that Rita Nowell is a resident of the State of Mississippi. Defendants admit that Rita Nowell may be served at her place of residence. Defendants deny the remaining allegations in this paragraph of the Complaint.

10. Defendants state that the allegations in this paragraph of the Complaint regarding Christine Ransom are not directed toward Defendants and, therefore, no response is required.

11. Defendants state that this paragraph of the Complaint contains legal contentions to which no response is required. To the extent that a response is deemed required, Defendants admit that Mickey Rumsey was employed by Pfizer as a pharmaceutical sales representative, and, at times, called on certain healthcare providers regarding Pfizer's products. Defendants admit that Mickey Rumsey is a resident of the State of Mississippi. Defendants admit that Mickey Rumsey may be served at her place of residence. Defendants deny the remaining allegations in this paragraph of the Complaint.

12. Defendants admit that Pfizer, Pharmacia, and Searle do business in the State of Mississippi. Defendants deny the remaining allegations in this paragraph of the Complaint.

13. Defendants are without knowledge or information to form a belief as the truth of the allegations in this paragraph of the Complaint regarding the judicial district in which the asserted claims allegedly arose and, therefore, deny the same. Defendants admit that Pfizer, Pharmacia, and Searle do business in the State of Mississippi. Defendants admit that Plaintiff claims that the

amount in controversy satisfies jurisdictional limits. Defendants deny that Bextra® caused Plaintiff injury or damage and deny the remaining allegations in this paragraph of the Complaint.

14. Defendants admit, as indicated in the package insert approved by the FDA, that Bextra® is indicated for use in the relief of the signs and symptoms of osteoarthritis and adult rheumatoid arthritis, as well as for the treatment of primary dysmenorrhea. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-promoted Bextra® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit that, during certain periods of time, Bextra® was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and distributed Bextra® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

15. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct, deny that Bextra® is defective, deny that Bextra® caused Plaintiff injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

Response to Background Allegations

16. Defendants admit, as indicated in the package insert approved by the FDA, that Bextra® is indicated for use in the relief of the signs and symptoms of osteoarthritis and adult rheumatoid arthritis, as well as for the treatment of primary dysmenorrhea. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-promoted Bextra® in the United

States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit that, during certain periods of time, Bextra® was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and distributed Bextra® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

17. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct, deny that Bextra® is defective, deny that Bextra® caused Plaintiff injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

18. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-promoted Bextra® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit that, during certain periods of time, Bextra® was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and distributed Bextra® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

19. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding Plaintiff's age and medical

condition, and, therefore, deny the same. Defendants deny that Bextra® caused Plaintiff injury or damage and deny the remaining allegations in this paragraph of the Complaint.

20. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

21. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-promoted Bextra® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit that, during certain periods of time, Bextra® was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and distributed Bextra® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants deny the remaining allegations in this paragraph of the Complaint.

22. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Bextra® and, therefore, deny the same. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

23. Defendants state that this paragraph of the Complaint contains legal contentions to which no response is required. To the extent that a response is deemed required, Defendants admit that Plaintiff claims that the amount in controversy meets jurisdictional limits. Defendants deny the remaining allegations in this paragraph of the Complaint.

24. Defendants admit that Bextra® is in a class of drugs that is, at times, referred to as non-steroidal anti-inflammatory drugs (NSAIDS"). Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the

Complaint regarding whether Decedent used Bextra® and, therefore, deny the same. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny that Bextra® caused Plaintiff injury or damage and deny the remaining allegations in this paragraph of the Complaint.

25. The allegations in this paragraph of the Complaint are not directed toward Defendants and, therefore, no response is required. To the extent a response is deemed required, Defendants state that Plaintiff fails to provide the proper context for the allegations in this paragraph of the Complaint. Defendants therefore lack sufficient information or knowledge to form a belief as to the truth of such allegations and, therefore, deny the same.

26. The allegations in this paragraph of the Complaint are not directed toward Defendants and, therefore, no response is required. To the extent a response is deemed required, Defendants state that Plaintiff fails to provide the proper context for the allegations in this paragraph of the Complaint. Defendants therefore lack sufficient information or knowledge to form a belief as to the truth of such allegations and, therefore, deny the same.

27. The allegations in this paragraph of the Complaint are not directed toward Defendants and, therefore, no response is required. To the extent a response is deemed required, Defendants state that Plaintiff fails to provide the proper context for the allegations in this paragraph of the Complaint. Defendants therefore lack sufficient information or knowledge to form a belief as to the truth of such allegations and, therefore, deny the same.

28. The allegations in this paragraph of the Complaint are not directed toward Defendants and, therefore, no response is required. To the extent a response is deemed required, Defendants state that Plaintiff fails to provide the proper context for the allegations in this paragraph of the Complaint. Defendants therefore lack sufficient information or knowledge to form a belief as to the truth of such allegations and, therefore, deny the same.

29. Plaintiff fails to provide the proper context for the allegations in this paragraph of the Complaint. Defendants lack sufficient information or knowledge to form a belief as to the truth of such allegations and, therefore, deny the same.

30. Defendants state that Plaintiff's allegations in this paragraph of the Complaint regarding "predecessors in interest" are vague and ambiguous. Defendants are without knowledge or information to form a belief as to the truth of such allegations, and therefore deny the same. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

31. Plaintiff does not allege having used Celebrex® in her Complaint. Nevertheless, Defendants admit that Celebrex® was launched in the United States in February 1999. Defendants state that Celebrex® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-promoted Bextra® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit that, during certain periods of time, Bextra® was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and distributed Bextra® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. The allegations in this paragraph of the Complaint regarding Merck and Vioxx® are not directed toward Defendants and, therefore, no response is required. To the extent a response is deemed required, Defendants state that Plaintiff fails to provide the proper context for the allegations in this paragraph of the Complaint regarding Merck and Vioxx®. Defendants therefore lack sufficient information or knowledge to form a belief as to the truth of such allegations and, therefore, deny the same. Defendants deny the remaining allegations in this paragraph of the Complaint.

32. Defendants admit that the New Drug Application for Bextra® was filed with the FDA on January 15, 2001. Defendants admit, as indicated in the package insert approved by the FDA, that Bextra® is indicated for use in the relief of the signs and symptoms of osteoarthritis and

adult rheumatoid arthritis, as well as for the treatment of primary dysmenorrhea. Defendants state that Plaintiff's allegations in this paragraph of the Complaint regarding "predecessors in interest" are vague and ambiguous. Defendants are without knowledge or information to form a belief as to the truth of such allegations, and therefore deny the same. Defendants deny the remaining allegations in this paragraph of the Complaint.

33. Defendants admit that Bextra® was approved by the FDA on November 16, 2001. Defendants admit, as indicated in the package insert approved by the FDA, that Bextra® is indicated for use in the relief of the signs and symptoms of osteoarthritis and adult rheumatoid arthritis, as well as for the treatment of primary dysmenorrhea. Defendants deny the remaining allegations in this paragraph of the Complaint.

34. Defendants admit, as indicated in the package insert approved by the FDA, that Bextra® is indicated for use in the relief of the signs and symptoms of osteoarthritis and adult rheumatoid arthritis, as well as for the treatment of primary dysmenorrhea. Defendants deny the remaining allegations in this paragraph of the Complaint.

35. Defendants admit, as indicated in the package insert approved by the FDA, that Bextra® is indicated for use in the relief of the signs and symptoms of osteoarthritis and adult rheumatoid arthritis, as well as for the treatment of primary dysmenorrhea. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants deny the remaining allegations in this paragraph of the Complaint.

36. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which at all times was adequate and comported with applicable standards of care and law. Defendants state that Plaintiff's allegations in this paragraph of the Complaint regarding "predecessors in interest" are vague and ambiguous. Defendants are without knowledge or information to form a belief as to the truth of such allegations, and therefore deny the same. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

37. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which at all times was adequate and comported with applicable standards of care and law. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-promoted Bextra® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit that, during certain periods of time, Bextra® was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and distributed Bextra® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants deny the remaining allegations in this paragraph of the Complaint.

38. Defendants state that the referenced article speaks for itself and respectfully refer the Court to the article for its actual language and text. Any attempt to characterize the article is denied. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants deny the remaining allegations in this paragraph of the Complaint.

39. The allegations in this paragraph of the Complaint are not directed towards Defendants and, therefore, no response is necessary. Should a response be deemed necessary, Defendants state that the referenced article speaks for itself and respectfully refer the Court to the article for its actual language and text. Any attempt to characterize the article is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

40. Defendants admit that the New Drug Application for Bextra® was filed with the FDA on January 15, 2001. Defendants admit that Bextra® was approved by the FDA, on November 16, 2001. Defendants deny any wrongful conduct and the remaining allegations in this paragraph of the Complaint.

41. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which at all times was adequate and comported with applicable standards of care and law. Defendants deny the allegations in this paragraph of the Complaint.

42. Defendants refer to the December 9, 2004 FDA Talk Paper for Bextra®, which speaks for itself and respectfully refer the Court to the Talk Paper for its actual language and text. Any attempt to characterize the Talk Paper is denied. Defendants deny the allegations in this paragraph of the Complaint.

43. Defendants state that the referenced article speaks for itself and respectfully refer the Court to the article for its actual language and text. Any attempt to characterize the article is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

44. Plaintiff fails to provide the proper context for the allegations concerning the "post-drug approval meta-analysis study" in this paragraph of the Complaint. Defendants are without sufficient information to confirm or deny such allegations and therefore deny the same. Defendants state that the referenced study speaks for itself and respectfully refer the Court to the study for its actual language and text. Any attempt to characterize the study is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

45. The allegations in this paragraph of the Complaint are not directed towards Defendants and, therefore, no response is necessary. Should a response be deemed necessary, Defendants state that the referenced article speaks for itself and respectfully refer the Court to the article for its actual language and text. Any attempt to characterize the article is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

46. The allegations in this paragraph of the Complaint are not directed towards Defendants and, therefore, no response is necessary. Should a response be deemed necessary, Defendants admit that a Joint Meeting of the Arthritis Advisory Committee and the Drug Safety and Risk Management Advisory Committee was held on February 16-18, 2005. Defendants state that the

referenced testimony speaks for itself and respectfully refer the Court to the testimony for its actual language and text. Any attempt to characterize the testimony is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

47. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

48. Defendants refer to the Alert for Healthcare Professionals issued by the FDA on April 7, 2005, which speaks for itself, and any attempt to characterize it is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

49. Defendants refer to the Alert for Healthcare Professionals issued by the FDA on April 7, 2005, which speaks for itself, and any attempt to characterize it is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

50. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants deny the allegations in this paragraph of the Complaint.

51. Defendants state that the referenced article speaks for itself and respectfully refer the Court to the article for its actual language and text. Any attempt to characterize the article is denied. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

52. The allegations in this paragraph of the Complaint are not directed towards Defendants and, therefore, no response is necessary. Should a response be deemed necessary, Defendants state that the referenced article speaks for itself and respectfully refer the Court to the article for its actual language and text. Any attempt to characterize the article is denied. Defendants deny the remaining allegations in this paragraph of the Complaint.

53. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which

was at all times adequate and comported with applicable standards of care and law. Defendants deny the allegations in this paragraph of the Complaint.

54. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct, deny that Bextra® is defective, and deny the remaining allegations in this paragraph of the Complaint.

55. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

56. Defendants deny the allegations in this paragraph of the Complaint.

57. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-promoted Bextra® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit that, during certain periods of time, Bextra® was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and distributed Bextra® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint

regarding whether Plaintiff used Bextra® and therefore deny the same. Defendants deny any wrongful conduct and deny the allegations in this paragraph of the Complaint.

58. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-promoted Bextra® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit that, during certain periods of time, Bextra® was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and distributed Bextra® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny the remaining allegations in this paragraph of the Complaint.

59. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-promoted Bextra® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit that, during certain periods of time, Bextra® was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and distributed Bextra® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants admit, as indicated in the package insert approved by the FDA, that Bextra® is indicated for use in the relief of the signs and symptoms

of osteoarthritis and adult rheumatoid arthritis, as well as for the treatment of primary dysmenorrhea. Defendants deny the remaining allegations in this paragraph of the Complaint.

60. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which at all times was adequate and comported with applicable standards of care and law. Defendants state that the allegations in this paragraph of the Complaint regarding "predecessors in interest" are vague and ambiguous. Defendants are without knowledge or information to form a belief as to the truth of such allegations, and therefore deny the same. Defendants deny any wrongful conduct, deny that Bextra® is defective, and deny the allegations in this paragraph of the Complaint.

61. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-promoted Bextra® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit that, during certain periods of time, Bextra® was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and distributed Bextra® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny the remaining allegations in this paragraph of the Complaint.

62. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which

at all times was adequate and comported with applicable standards of care and law. Defendants deny the remaining allegations in this paragraph of the Complaint.

63. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

64. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

65. Defendants deny the allegations in this paragraph of the Complaint.

66. Defendants admit that the sale of Bextra® was voluntarily suspended in the U.S. market as of April 7, 2005. Defendants deny any wrongful conduct and deny the remaining allegations contained in this paragraph of the Complaint.

67. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct, deny that Bextra® is defective, and deny the remaining allegations in this paragraph of the Complaint.

68. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which

was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

69. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

70. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-promoted Bextra® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit that, during certain periods of time, Bextra® was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and distributed Bextra® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

71. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-promoted Bextra® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit that, during certain periods of time, Bextra® was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and distributed Bextra® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants deny the remaining allegations in this paragraph of the Complaint.

72. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-promoted Bextra® in the United States to be prescribed by healthcare providers who are by

law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit that, during certain periods of time, Bextra® was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and distributed Bextra® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit, as indicated in the package insert approved by the FDA, that Bextra® is indicated for use in the relief of the signs and symptoms of osteoarthritis and adult rheumatoid arthritis, as well as for the treatment of primary dysmenorrhea. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

73. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding and whether Plaintiff used Bextra® and therefore deny the same. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

74. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding and whether Plaintiff used Bextra® and therefore deny the same. Defendants deny any wrongful conduct, deny that Bextra® is defective, deny that Bextra® caused Plaintiff injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

Response to First Cause of Action: Negligence

75. Defendants incorporate by reference their responses to each paragraph of Plaintiff's Complaint as if fully set forth herein.

76. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct, deny that Bextra® is defective, and deny the remaining allegations in this paragraph of the Complaint.

77. Defendants state that this paragraph of the Complaint contains legal contentions to which no response is required. To the extent that a response is deemed required, Defendants admit that they had duties as are imposed by law but deny having breached such duties. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Bextra® and, therefore, deny the same. Defendants deny the remaining allegations in this paragraph of the Complaint.

78. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Bextra® and, therefore, deny the same. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct, deny that Bextra® is defective, and deny the remaining allegations in this paragraph of the Complaint, including all subparts.

79. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Bextra® and, therefore, deny the same. Defendants state that Bextra® was and is safe and

effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct, deny that Bextra® is unreasonably dangerous, and deny the remaining allegations in this paragraph of the Complaint.

80. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

81. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

82. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

83. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

Response to Second Cause of Action: Strict Products Liability Defective Design

84. Defendants incorporate by reference their responses to each paragraph of Plaintiff's Complaint as if fully set forth herein.

85. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-promoted Bextra® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit that, during certain periods of time, Bextra® was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and distributed Bextra® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants deny any wrongful conduct, deny that Bextra® is defective or unreasonably dangerous, and deny the remaining allegations in this paragraph of the Complaint.

86. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct, deny that Bextra® is defective or unreasonably dangerous, and deny the remaining allegations in this paragraph of the Complaint, including all subparts.

87. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Bextra® and, therefore, deny the same. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants state that, in the ordinary case, Bextra® was expected to reach users and consumers without substantial change from the time of sale. Defendants deny any wrongful conduct, deny that Bextra® is unreasonably dangerous, and deny the remaining allegations in this paragraph of the Complaint.

88. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Bextra® and, therefore, deny the same. Defendants deny the remaining allegations in this paragraph of the Complaint.

89. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct, deny that Bextra® is defective or unreasonably dangerous, deny that Bextra® caused Plaintiff injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

90. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct, deny that Bextra® is defective or unreasonably dangerous, deny that Bextra® caused Plaintiff injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

91. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct, deny that Bextra® is defective or unreasonably dangerous, deny that Bextra® caused Plaintiff injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

92. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct, deny that Bextra® is defective or unreasonably dangerous, deny that Bextra® caused Plaintiff injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

Response to Third Cause of Action: Strict Products Liability Failure to Warn

93. Defendants incorporate by reference their responses to each paragraph of Plaintiff's Complaint as if fully set forth herein.

94. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Bextra® and, therefore, deny the same. Defendants state that Bextra® was and is safe and

effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct, deny that Bextra® is defective or unreasonably dangerous, and deny the remaining allegations in this paragraph of the Complaint.

95. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Bextra® and, therefore, deny the same. Defendants deny the remaining allegations in this paragraph of the Complaint.

96. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Bextra® and, therefore, deny the same. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct, deny that Bextra® is defective or unreasonably dangerous, and deny the remaining allegations in this paragraph of the Complaint.

97. Defendants state that this paragraph of the Complaint contains legal contentions to which no response is required. To the extent that a response is deemed required, Defendants deny the allegations in this paragraph of the Complaint.

98. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants

deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

99. Defendants state that this paragraph of the Complaint contains legal contentions to which no response is required. To the extent that a response is deemed required, Defendants Pfizer, Pharmacia, and Searle admit that they had duties as are imposed by law but deny having breached such duties. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Bextra® and, therefore, deny the same. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

100. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

101. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

102. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

103. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

Response to Fourth Cause of Action: Breach of Express Warranty of Merchantability

104. Defendants incorporate by reference their responses to each paragraph of Plaintiff's Complaint as if fully set forth herein.

105. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-promoted Bextra® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants

admit that, during certain periods of time, Bextra® was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and distributed Bextra® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants deny the remaining allegations in this paragraph of the Complaint.

106. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-promoted Bextra® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit that, during certain periods of time, Bextra® was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and distributed Bextra® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny the remaining allegations in this paragraph of the Complaint.

107. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

108. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants

deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

109. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

110. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

Response to Fifth Cause of Action: Breach of Implied Warranty of Merchantability

111. Defendants incorporate by reference their responses to each paragraph of Plaintiff's Complaint as if fully set forth herein.

112. Defendants state that this paragraph of the Complaint contains legal contentions to which no response is required. To the extent that a response is deemed required, Defendants deny the allegations in this paragraph of the Complaint.

113. Defendants state that this paragraph of the Complaint contains legal contentions to which no response is required. To the extent that a response is deemed required, Defendants deny the allegations in this paragraph of the Complaint.

114. Defendants admit that, during certain periods of time, Pfizer and Pharmacia marketed and co-promoted Bextra® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants admit that, during certain periods of time, Bextra® was manufactured and packaged for Searle, which developed, tested, marketed, co-promoted and distributed Bextra® in the United States to be prescribed by healthcare providers who are by law authorized to prescribe drugs in accordance with their approval by the FDA. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants Pfizer, Pharmacia, and Searle admit that they

provided FDA-approved prescribing information regarding Bextra®. Defendants deny the remaining allegations in this paragraph of the Complaint.

115. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Bextra® and, therefore, deny the same. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny the remaining allegations in this paragraph of the Complaint.

116. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct, deny any breach of warranty, deny that Bextra® is defective or unreasonably dangerous, and deny the remaining allegations in this paragraph of the Complaint.

117. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Bextra® and, therefore, deny the same. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct, deny any breach of warranty, and deny the remaining allegations in this paragraph of the Complaint, including all subparts.

118. Defendants deny any wrongful conduct, deny any breach of warranty, deny that Bextra® caused Plaintiff injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

119. Defendants deny any wrongful conduct, deny any breach of warranty, deny that Bextra® caused Plaintiff injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

120. Defendants deny any wrongful conduct, deny any breach of warranty, deny that Bextra® caused Plaintiff injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

121. Defendants deny any wrongful conduct, deny any breach of warranty, deny that Bextra® caused Plaintiff injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

122. Defendants deny any wrongful conduct, deny any breach of warranty, deny that Bextra® caused Plaintiff injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

Response to Sixth Cause of Action: Fraud

123. Defendants incorporate by reference their responses to each paragraph of Plaintiff's Complaint as if fully set forth herein.

124. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Bextra® and, therefore, deny the same. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

125. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Bextra® and, therefore, deny the same. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

126. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

127. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Bextra® and, therefore, deny the same. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

128. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants

deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

129. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Bextra® and, therefore, deny the same. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint, including all subparts.

130. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

131. Defendants state that this paragraph of the Complaint contains legal contentions to which no response is required. To the extent that a response is deemed required, Defendants Pfizer, Pharmacia, and Searle admit that they had duties as are imposed by law but deny having breached such duties. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Bextra® and, therefore, deny the same. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

132. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Bextra® and, therefore, deny the same. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

133. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

134. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

135. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

136. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

137. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

Response to Seventh Cause of Action: Negligent Misrepresentation

138. Defendants incorporate by reference their responses to each paragraph of Plaintiff's Complaint as if fully set forth herein.

139. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Bextra® and, therefore, deny the same. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-

approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

140. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Bextra® and, therefore, deny the same. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

141. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

142. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

143. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Bextra® and, therefore, deny the same. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants

state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

144. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Bextra® and, therefore, deny the same. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint, including all subparts.

145. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

146. Defendants state that this paragraph of the Complaint contains legal contentions to which no response is required. To the extent that a response is deemed required, Defendants Pfizer, Pharmacia, and Searle admit that they had duties as are imposed by law but deny having breached such duties. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Bextra® and, therefore, deny the same. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with

applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

147. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph of the Complaint regarding whether Plaintiff used Bextra® and, therefore, deny the same. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

148. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

149. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

150. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

151. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

152. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

153. Defendants state that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendants state that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

154. Defendants deny any wrongful conduct and deny the remaining allegations in this paragraph of the Complaint.

Response to Allegations Regarding Damages

155. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

156. Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

Response to Prayer for Relief

Answering the unnumbered paragraph the Complaint entitled "Prayer for Relief," Defendants deny any wrongful conduct, deny that Bextra® caused Plaintiff injury or damage, and deny the remaining allegations in this paragraph of the Complaint.

III.
GENERAL DENIAL

Defendants deny the allegations and/or legal conclusions set forth in Plaintiff's Complaint that have not been previously admitted, denied, or explained.

IV.
AFFIRMATIVE DEFENSES

Defendants reserve the right to rely upon any of the following or additional defenses to claims asserted by Plaintiff to the extent that such defenses are supported by information developed through discovery or evidence at trial. Defendants affirmatively show that:

First Defense

1. The Complaint fails to state a claim upon which relief can be granted.

Second Defense

2. Bextra® is a prescription medical product. The federal government has preempted the field of law applicable to the labeling and warning of prescription medical products. Defendants' labeling and warning of Bextra® was at all times in compliance with applicable federal law. Plaintiff's causes of action against Defendants, therefore, fail to state a claim upon

which relief can be granted; such claims, if allowed, would conflict with applicable federal law and violate the Supremacy Clause of the United States Constitution.

Third Defense

3. At all relevant times, Defendants provided proper warnings, information, and instructions for the drug in accordance with generally recognized and prevailing standards in existence at the time.

Fourth Defense

4. At all relevant times, Defendants' warnings and instructions with respect to the use of Bextra® conformed to the generally recognized, reasonably available, and reliable state of knowledge at the time the drug was manufactured, marketed, and distributed.

Fifth Defense

5. Plaintiff's action is time-barred as it is filed outside of the time permitted by the applicable Statute of Limitations, and same is plead in full bar of any liability as to Defendants.

Sixth Defense

6. Plaintiff's action is barred by the statute of repose.

Seventh Defense

7. Plaintiff's claims against Defendants are barred to the extent Plaintiff was contributorily negligent, actively negligent or otherwise failed to mitigate her damages, and any recovery by Plaintiff should be diminished accordingly.

Eighth Defense

8. The proximate cause of the loss complained of by Plaintiff is not due to any acts or omissions on the part of Defendants. Rather, said loss is due to the acts or omissions on the part of third parties unrelated to Defendants and for whose acts or omissions Defendants are not liable in any way.

Ninth Defense

9. The acts and/or omissions of unrelated third parties as alleged constituted independent, intervening causes for which Defendants cannot be liable.

Tenth Defense

10. Any injuries or expenses incurred by Plaintiff were not caused by Bextra®, but were proximately caused, in whole or in part, by an idiosyncratic reaction, operation of nature, or act of God.

Eleventh Defense

11. Defendants affirmatively deny that they violated any duty owed to Plaintiff.

Twelfth Defense

12. A manufacturer has no duty to warn patients or the general public of any risk, contraindication, or adverse effect associated with the use of a prescription medical product. Rather, the law requires that all such warnings and appropriate information be given to the prescribing physician and the medical profession, which act as a "learned intermediary" in determining the use of the product. Bextra® is a prescription medical product, available only on the order of a licensed physician. Bextra® provided an adequate warning to Plaintiff's treating and prescribing physicians.

Thirteenth Defense

13. The product at issue was not in a defective condition or unreasonably dangerous at the time it left the control of the manufacturer or seller.

Fourteenth Defense

14. Bextra® was at all times material to the Complaint reasonably safe and reasonably fit for its intended use and the warnings and instructions accompanying Bextra® at the time of the occurrence of the injuries alleged by Plaintiff were legally adequate for its approved usages.

Fifteenth Defense

15. Plaintiff's causes of action are barred in whole or in part by the lack of a defect as the Bextra® allegedly ingested by Plaintiff was prepared in accordance with the applicable standard of care.

Sixteenth Defense

16. Plaintiff's alleged injuries/damages, if any, were the result of misuse or abnormal use of the product Bextra® after the product left the control of Defendants and any liability of Defendants is therefore barred.

Seventeenth Defense

17. Plaintiff's alleged damages were not caused by any failure to warn on the part of Defendants.

Eighteenth Defense

18. Plaintiff's alleged injuries/damages, if any, were the result of preexisting or subsequent conditions unrelated to Bextra®.

Nineteenth Defense

19. Plaintiff knew or should have known of any risk associated with Bextra®; therefore, the doctrine of assumption of the risk bars or diminishes any recovery.

Twentieth Defense

20. Plaintiff is barred from recovering against Defendants because Plaintiff's claims are preempted in accordance with the Supremacy Clause of the United States Constitution and by the Federal Food, Drug and Cosmetics Act, 21 U.S.C. § 301 et. seq.

Twenty-first Defense

21. Plaintiff's claims are barred in whole or in part under the applicable state law because the subject pharmaceutical product at issue was subject to and received pre-market approval by the Food and Drug Administration under 52 Stat. 1040, 21 U.S.C. § 301.

Twenty-second Defense

22. The manufacture, distribution, and sale of the pharmaceutical product referred to in Plaintiff's Complaint were at all times in compliance with all federal regulations and statutes, and Plaintiff's causes of action are preempted.

Twenty-third Defense

23. Plaintiff's claims are barred in whole or in part by the deference given to the primary jurisdiction of the Food and Drug Administration over the subject pharmaceutical product at issue under applicable federal laws, regulations, and rules.

Twenty-fourth Defense

24. Plaintiff's claims are barred in whole or in part because there is no private right of action concerning matters regulated by the Food and Drug Administration under applicable federal laws, regulations, and rules.

Twenty-fifth Defense

25. Plaintiff's claims are barred in whole or in part because Defendants provided adequate "direction or warnings" as to the use of the subject pharmaceutical product within the meaning of Comment j to Section 402A of the Restatement (Second) of Torts.

Twenty-sixth Defense

26. Plaintiff's claims are barred or limited to a product liability failure to warn claim because Bextra® is a prescription pharmaceutical drug and falls within the ambit of Restatement (Second) of Torts § 402A, Comment k.

Twenty-seventh Defense

27. Plaintiff's claims are barred in whole or in part because the subject pharmaceutical product at issue "provides net benefits for a class of patients" within the meaning of Comment f to § 6 of the Restatement (Third) of Torts: Products Liability.

Twenty-eighth Defense

28. Plaintiff's claims are barred under § 4, et seq., of the Restatement (Third) of Torts: Products Liability.

Twenty-ninth Defense

29. To the extent that Plaintiff is seeking punitive damages, Plaintiff has failed to plead facts sufficient under the law to justify an award of punitive damages.

Thirtieth Defense

30. The imposition of punitive damages in this case would violate Defendants' rights to procedural due process under the Fourteenth Amendment of the United States Constitution and Constitution of the State of Mississippi, and would additionally violate Defendants' right to substantive due process under the Fourteenth Amendment of the United States Constitution.

Thirty-first Defense

31. Plaintiff's claims for punitive damages are barred, in whole or in part, by the Fifth and Fourteenth Amendments to the United States Constitution.

Thirty-second Defense

32. The imposition of punitive damages in this case would violate the First Amendment to the United States Constitution and Constitution of the State of Mississippi.

Thirty-third Defense

33. Plaintiff's punitive damage claims are preempted by federal law.

Thirty-fourth Defense

34. In the event that reliance was placed upon Defendants' nonconformance to an express representation, this action is barred as there was no reliance upon representations, if any, of Defendants.

Thirty-fifth Defense

35. Plaintiff failed to provide Defendants with timely notice of any alleged nonconformance to any express representation.

Thirty-sixth Defense

36. To the extent that Plaintiff's claims are based on a theory providing for liability without proof of causation, the claims violate Defendants' rights under the United States Constitution.

Thirty-seventh Defense

37. Plaintiff's claims are barred, in whole or in part, because the advertisements, if any, and labeling with respect to the subject pharmaceutical products were not false or misleading and,

therefore, constitute protected commercial speech under the applicable provisions of the United States Constitution.

Thirty-eighth Defense

38. To the extent that Plaintiff seeks punitive damages for the conduct which allegedly caused injuries asserted in the Complaint, punitive damages are barred or reduced by applicable law or statute or, in the alternative, are unconstitutional insofar as they violate the due process protections afforded by the United States Constitution, the excessive fines clause of the Eighth Amendment of the United States Constitution, the Commerce Clause of the United States Constitution, and the Full Faith and Credit Clause of the United States Constitution and Constitution of the State of Mississippi. Any law, statute, or other authority purporting to permit the recovery of punitive damages in this case is unconstitutional, facially and as applied, to the extent that, without limitation, it: (1) lacks constitutionally sufficient standards to guide and restrain the jury's discretion in determining whether to award punitive damages and/or the amount, if any; (2) is void for vagueness in that it failed to provide adequate advance notice as to what conduct will result in punitive damages; (3) permits recovery of punitive damages based on out-of-state conduct, conduct that complied with applicable law, or conduct that was not directed, or did not proximately cause harm, to Plaintiff; (4) permits recovery of punitive damages in an amount that is not both reasonable and proportionate to the amount of harm, if any, to Plaintiff and to the amount of compensatory damages, if any; (5) permits jury consideration of net worth or other financial information relating to Defendants; (6) lacks constitutionally sufficient standards to be applied by the trial court in post-verdict review of any punitive damages awards; (7) lacks constitutionally sufficient standards for appellate review of punitive damages awards; and (8) otherwise fails to satisfy Supreme Court precedent, including, without limitation, *Pacific Mutual Life Ins. Co. v. Haslip*, 499 U.S. 1, 111 (1991), *TXO Production Corp. v. Alliance Resources, Inc.*, 509 U.S. 443 (1993); *BMW of North America, Inc. v. Gore*, 519 U.S. 559 (1996); and *State Farm Mut. Auto Ins. Co. v. Campbell*, 538 U.S. 408 (2003).

Thirty-ninth Defense

39. The methods, standards, and techniques utilized with respect to the manufacture, design, and marketing of Bextra®, if any, used in this case, included adequate warnings and instructions with respect to the product's use in the package insert and other literature, and conformed to the generally recognized, reasonably available, and reliable state of the knowledge at the time the product was marketed.

Fortieth Defense

40. The claims asserted in the Complaint are barred because Bextra® was designed, tested, manufactured, and labeled in accordance with the state-of-the art industry standards existing at the time of the sale.

Forty-first Defense

41. If Plaintiff has sustained injuries or losses as alleged in the Complaint, upon information and belief, such injuries and losses were caused by the actions of persons not having real or apparent authority to take said actions on behalf of Defendants and over whom Defendants had no control and for whom Defendants may not be held accountable.

Forty-second Defense

42. The claims asserted in the Complaint are barred, in whole or in part, because Bextra® was not unreasonably dangerous or defective, was suitable for the purpose for which it was intended, and was distributed with adequate and sufficient warnings.

Forty-third Defense

43. Plaintiff's claims are barred, in whole or in part, by the equitable doctrines of laches, waiver, and/or estoppel.

Forty-fourth Defense

44. Plaintiff's claims are barred because Plaintiff's injuries, if any, were the result of the pre-existing and/or unrelated medical, genetic, and/or environmental conditions, diseases or illnesses, subsequent medical conditions or natural courses of conditions of Plaintiff, and were independent of or far removed from Defendants' conduct.

Forty-fifth Defense

45. The claims asserted in the Complaint are barred, in whole or in part, because Bextra® did not proximately cause injuries or damages to Plaintiff.

Forty-sixth Defense

46. The claims asserted in the Complaint are barred, in whole or in part, because Plaintiff did not incur any ascertainable loss as a result of Defendants' conduct.

Forty-seventh Defense

47. The claims asserted in the Complaint are barred, in whole or in part, because the manufacturing, labeling, packaging, and any advertising of the product complied with the applicable codes, standards and regulations established, adopted, promulgated or approved by any applicable regulatory body, including but not limited to the United States, any state, and any agency thereof.

Forty-eighth Defense

48. The claims must be dismissed because Plaintiff would have taken Bextra® even if the product labeling contained the information that Plaintiff contends should have been provided.

Forty-ninth Defense

49. The claims asserted in the Complaint are barred because the utility of Bextra® outweighed its risks.

Fiftieth Defense

50. Plaintiff's damages, if any, are barred or limited by the payments received from collateral sources.

Fifty-first Defense

51. Defendants' liability, if any, can only be determined after the percentages of responsibility of all persons who caused or contributed toward Plaintiff's alleged damages, if any, are determined. Defendants seek an adjudication of the percentage of fault of the claimants and each and every other person whose fault could have contributed to the alleged injuries and damages, if any, of Plaintiff.

Fifty-second Defense

52. Plaintiff's claims are barred, in whole or in part, by the doctrine of abstention in that the common law gives deference to discretionary actions by the United States Food and Drug Administration under the Federal Food, Drug, and Cosmetic Act.

Fifty-third Defense

53. The claims asserted in the Complaint are barred, in whole or in part, because Bextra® is comprehensively regulated by the FDA pursuant to the Federal Food, Drug & Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301 *et seq.*, and regulations promulgated there under, and Plaintiff's claims conflict with the FDCA, with the regulations promulgated by FDA to implement the FDCA, with the purposes and objectives of the FDCA and FDA's implementing regulations, and with the specific determinations by FDA specifying the language that should be used in the labeling accompanying Bextra®. Accordingly, Plaintiff's claims are preempted by the Supremacy Clause of the United States Constitution, Article VI, clause 2, and the laws of the United States.

Fifty-fourth Defense

54. Plaintiff's misrepresentation allegations are not stated with the degree of particularity required by F.R.C.P. 9(b) and/or M.R.C.P. 9(b) and should be dismissed.

Fifty-fifth Defense

55. To the extent that Plaintiff relies upon any theory of breach of warranty, her claims are barred because Defendants did not make or breach any express or implied warranties, and because Plaintiff failed to give reasonable notice to Defendants of any alleged breach or breaches of warranty as required by Miss. Code Ann § 75-2-607(3)(a).

Fifty-sixth Defense

56. Any verdict or judgment rendered against Defendants must be reduced under the laws of the State of Mississippi by those amounts which have been, or will, with reasonable certainty, replace or indemnify Plaintiff, such as insurance, social security, worker's compensation, or employee benefits programs. Plaintiff may have settled her claims for alleged injuries and

damages with certain parties. Defendants therefore are, in any event, entitled to a credit in the amount of any such settlement heretofore made between Plaintiff and any such parties.

Fifty-seventh Defense

57. Plaintiff's claims for punitive damages are limited or barred by the standards governing exemplary damage awards which arise under the United States Constitution and decisions of the United States Supreme Court such as *BMW of North America v. Gore*, 116 U.S. 1589 (1996); *Cooper Industries, Inc., v. Leatherman Tool Group, Inc.*, 532 U.S. 424 (2001); and *State Farm Mut. Auto Ins. Co. v. Campbell*, 123 S.Ct. 1513 (U.S. 2003), or the Mississippi Constitution, statutes, and decisions of Mississippi courts.

Fifty-eighth Defense

58. Defendants assert that Plaintiff's claim for punitive damages is governed and limited by Miss. Code Ann. § 11-1-65, and Defendants hereby plead and invoke the provisions of the same.

Fifty-ninth Defense

59. Venue is improper in the Circuit Court of Harrison County, Mississippi.

Sixtieth Defense

60. This Court lacks personal jurisdiction over some of the Defendants.

Sixty-first Defense

61. Bextra® and Defendants' actions conformed to the state of the art medical and scientific knowledge at all times relevant to this lawsuit and/or Bextra® complied with applicable product safety statutes and regulations as described in Restatement (Third) of Torts: Products Liability § 4.

Sixty-second Defense

62. Defendants satisfied their duty to warn under the learned intermediary doctrine and Plaintiff's claims are therefore barred.

Sixty-third Defense

63. Plaintiff's allegations of fraud, deceit, and fraudulent misrepresentation are not stated with the degree of particularity required by F.R.C.P. 9(b) and/or M.R.C.P. 9(b) and should be dismissed.

Sixty-fourth Defense

64. Defendants hereby plead all defenses contained in Miss. Code Ann. § 11-1-63 and hereby invoke the provisions of Miss. Code Ann. § 85-5-7.

Sixty-fifth Defense

65. Plaintiff failed to join all indispensable parties; as a result of such failure to join, complete relief cannot be accorded to those already parties to the action and will result in prejudice to Defendants in any possible future litigation.

Sixty-sixth Defense

66. Any judicially-created definitions of manufacturing defect and design defect, and standards for determining whether there has been an actionable failure to warn, are unconstitutional in that, among other things, they are void for vagueness and undue burden on interstate commerce, as well as an impermissible effort to regulate in an area that previously has been preempted by the federal government.

Sixty-seventh Defense

67. Plaintiff's claims are barred in whole or in part because the subject pharmaceutical product at issue "provides net benefits for a class of patients" within the meaning of Comment f to § 6 of the Restatement (Third) of Torts: Products Liability.

Sixty-eighth Defense

68. To the extent that Plaintiff seeks punitive damages for an alleged act or omission of Defendants, no act or omission was oppressive, fraudulent, or malicious, and, therefore, any award of punitive damages is barred.

Sixty-ninth Defense

69. Plaintiff's claims are barred in whole or in part because Plaintiff lacks standing to bring such claims.

Seventieth Defense

70. Service of process on Defendants Rita Nowell and Mickey Rumsey was improper/insufficient.

Seventy-first Defense

71. Defendants reserve the right to supplement their assertion of defenses as they continue with their factual investigation of Plaintiff's claims.

V.
JURY DEMAND

Defendants hereby demand a trial by jury.

VI.
PRAYER

WHEREFORE, Defendants pray that Plaintiff take nothing by her suit; that Defendants be discharged with their costs expended in this matter, and for such other and further relief to which Defendants may be justly entitled.

This, the 1st day of August, 2007.

Respectfully submitted,

By: /s/ Walter T. Johnson
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ATTORNEYS FOR PFIZER INC., PHARMACIA CORPORATION, G.D. SEARLE LLC, RITA NOWELL, AND MICKEY RUMSEY

CERTIFICATE OF SERVICE

I hereby certify that on August 1, 2007, I electronically filed the foregoing with the Clerk of the Court using the CM/ECF system and forwarded on July 27, 2007, via United States first-class mail, postage prepaid, a true and correct copy to the following:

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ATTORNEYS FOR RITA NOWELL AND MICKEY RUMSEY

This, the 1st day of August, 2007.

/s/ Walter T. Johnson____
WALTER T. JOHNSON